dHealth 2022
G. Schreier et al. (Eds.)

doi:10.3233/SHTI220362

Patient Safety Classifications for Health Information Technology (HIT) and Medical Devices: A Review on Available Systems

Sharare TAHERI MOGHADAM[a], Nakysa HOOMAN[b] and Abbas SHEIKHTAHERI[c,1]
a PhD candidate, Department of Health Information Management, School of Health Management and Information Sciences, Iran University of Medical Sciences, Tehran, Iran
b Pediatric Nephrology Department, Aliasghar Clinical Research Development Center (AACRDC), Aliasghar Children Hospital, Iran University of Medical Sciences, Tehran, Iran
c Department of Health Information Management, School of Health Management and Information Sciences, Iran University of Medical Sciences, Tehran, Iran

Abstract. Background: Patient safety classifications are used to collect, classify and analyze patient safety data. Objective: This review was conducted to identify and compare the subject and coverage of existing patient safety classifications for Health Information Technology (HIT) and medical devices in which HIT may cover. Methods: All studies in patient safety that developed or extended any type of classification in HIT and medical devices were included. We identified and classified the covered concepts in these systems. Results: We identified 7 articles that met all of the inclusion criteria, resulting in 6 classifications. The most common patient safety subjects included adverse events and medication errors. Incident types and contributing factors/hazards were the most frequently covered concepts. Conclusions: Patient safety classifications in HIT cover more concepts and classes than medical device classifications. It is therefore recommended to improve existing classification systems in terms of covered concepts and classes.

Keywords: Adverse event, Classification, Coverage, Health information technology, Medical device, Medical Errors, Patient safety.

1. Introduction

Patient safety indicates the absence of any injuries inflicted by the provision of healthcare or medical errors [1]. Patient safety issues can arise as a result of application of information technology [2]. The enormous range of medical devices available, as well as the possibility for failure, malfunction, and some other adverse events involved with each device presents a challenge for monitoring patient safety events [3]. Consider the juxtaposition error in Computerized Physician Order Entry (CPOE), in which the incorrect object or patient is selected due to their close location on the screen [2]. There

1 Corresponding Author: Abbas Sheikhtaheri, Department of Health Information Management, School of Health Management and Information Sciences, Iran University of Medical Sciences, Tehran, Iran. (E-mail: Sheikhtaheri.a@iums.ac.ir).

are many reporting systems and databases that give data on medical device failures and patient safety incidents caused by information technology and medical equipment [2-4]. Reports of patient deaths and morbidity due to health information technology problems indicate the importance of identifying these problems [4]. HIT errors account for a large percentage [5]. For example, in one year, 4,161 patient safety incidents were reported, 16% of which were related to HIT errors [2]. Patient safety information systems and reporting tools can gather and interpret data and information about adverse outcomes [6]. In these systems, there is a possibility of not reporting errors related to HIT because those errors may not be considered important by users [7] and there may be no options for users to select appropriate HIT or device related safety concepts in these systems. Additionally, users may input texts that cannot be easily analyzed [8].

Low information quality, the complexity of analyzing text information, the lack of a common vocabulary, and the complexity of categorizing patient safety reports are all difficulties that support the need for a standard classification for patient safety concepts [9-11]. There are several general patient safety classifications; however, they may not cover HIT and device (technology) safety concepts appropriately. For example, there are some HIT safety concepts such as data-capture device down, input/ output device/ network down, software/ hardware interface issues and errors in medication process which are not covered in general classifications.

Therefore, several classifications have been developed to analyze these patient safety incidents [4, 7]. Classifying the safety problems of information technology and medical devices helps to create a framework for better collection and analysis of these data [3, 5]. The purpose of this study was to review the types of patient safety classification systems in this area.

2. Methods

This scoping review was carried out in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Review (PRISMA) criteria [12]. To explore relevant ontologies and classifications, we searched Google, Google Scholar, Web of Science, Scopus, Science Direct and PubMed. All published papers until the end of 2020 were considered, and alerts were used to obtain recent publications. Reference checking was also carried out in order to include all eligible papers. We looked for keywords and Mesh terms like "patient safety", "medical error", "medical mistake", " medical incidents", "never events", "medical event", "patient harm", "drug side effects", "adverse drug reactions", "adverse effects", "medication error", "adverse device effect", "classification", "hierarchy", "controlled vocabulary", "medical ontology" as well as their synonyms. Related articles in any language about patient safety classifications were included. Studies in which a classification was developed or extended were included. Letters to the editors and abstracts given at conferences were excluded. Studies that assessed a classification system without expanding or developing it further were also omitted. Studies were only included if the medical domain was HIT or medical device safety problems. According to WHO, medical devices generally include software; therefore, we considered medical devices, accordingly [13]. We included medical device technology in which information technology issues were covered.

Two authors worked independently on the selection, screening, and data extraction. All of the disagreements were settled by consensus. The data were entered into the Excel

software. To analyze the data, we used descriptive narrative synthesis. Two authors retrieved and categorized data separately before agreeing on the final analysis.

3. Results

Figure 1 shows the paper selection process. As it shows, we found seven articles which described six classifications [2-5, 7, 14, 15]. These are FDA Adverse Event Problem Codes (FDA-EPC), Classification of Adverse Events with the DaVinci (CAED), Classification of Technology-induced Errors (CTE), Classification for Health Information Technology Safety Problems (CHIT-SP), Medication Incidents associated with Information Technology Classification (MI-ITC), and Taxonomy for Medication-related Patient Safety events related to Health Information Technology (TMPS-HIT).

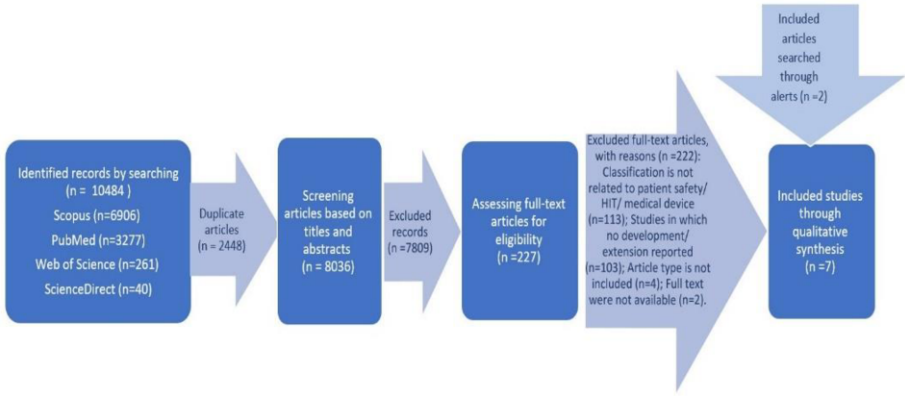

Figure 1. PRISMA flowchart for paper selection

The majority of these classifications were developed in the US (3 studies) [3, 14, 15] and Australia (2 studies) [4, 7]. Adverse event (FDA- EPC and CAED) [3, 14] and medication errors (MI-ITC and TMPS-HIT) [2, 15] are the most common subjects. There are three classifications for medical devices (FDA-EPC, CTE and CAED) [3, 5, 14] and three for HIT (MI-ITC, CHIT-SP and TMPS-HIT) [2, 4, 15].

FDA-EPC covers six concepts in four levels and classifies FDA Device Problem Codes [3] and CAED classifies DaVinci surgical machine errors in 2 groups and 7 subgroups [14]. CTE covers Electronic Health Record (EHR) downtime and system-to-system interface errors, or device defects or failures [5].

CHIT-SP is a general classification with 32concepts[4, 7]. MI-ITC is for medication incidents in four main classes containing the principal source of the IT-related problems and the nature of errors [2]. TMPS-HIT is a taxonomy with five main classes for medication events [15]. Table 1 shows covered concepts for included classifications. According to Table 2, the most prevalent concepts are "incident type" and "contributing factors/hazards".

Table 1. First and second level concepts for included classifications

Classification name/ Reference/ Subject	First and second-level concepts
FDA- EPC / [3]/ Device and patient adverse events	Device operational issue; Facilities issue; Human factors issue.
CAED / [14]/ Adverse events related to DaVinci	Severity (Mild; Moderate; Severe; Life-threatening/death).
	Relationship of event to device (Not related; Possibly; Definitely).
CTE / [5]/ Medical device safety incidents	Device defects/failures; Open/ incomplete/missing orders; Incorrect identification; Time measurement errors; Incorrect selected items; Failure to heed a computer-generated alert; Failure to find/use recent patient data; Other
CHIT-SP / [4, 7]/ Health technology safety problems	Information input (Data-capture device down e.g., problem communicating with PACS; Data entry/record manipulation)
	Transfer (Network down/too slow; Software interface issues)
	Output (Output device down/unavailable; Record unavailable/output/display error; Data retrieval error)
	General technical (Computer system down/slow; Software not available; Access problem; Software issue)
	Human contributing factors (Staffing/training; Cognitive load; Fail to do a duty)
MI-ITC / [2]/ Medication incidents	Nature of error (Data entry/record manipulation; Wrong input; Failure to communicate after input; Data retrieval; No output; Wrong output; Unclear output; Failure to react on signal; Data transfer; Mistranslation of data between 2 systems; No data transfer between 2 systems)
	Overview of IT systems involved (Automated dispensing cabinets; CPOE; Order system website; EHR; Fax; Infusion pump; Laboratory diagnostic analyzer; Medication administration registration; Pharmacy bar code scanning system; Pharmacy information system; Prescription scanner; Printer)
	Problems in different phases of medication process (Prescribing; Transcription; Entering of prescriptions into pharmacy information system; Compounding; Dispensing; Administration; Patient monitoring; Storage and logistics)
	Principal source of IT problem/nature of the error (Human-machine; interaction input; Human-machine; interaction output; machine input; machine output; Machine transfer)
TMPS-HIT / [15]/ Medication events	Information input problems (Data capture device down/ unavailable (machine); Data entry/record manipulation (human))
	Information transfer problems (machine) (Network down/ too slow; Software interface issues)
	Information output problems (Output device down/ unavailable (machine); Record unavailable (machine); Output/display error (machine); Data retrieval error)
	General technical (machine) (Computer system down/ slow; Software not available; Access problem; Software issue; Data loss; Hardware malfunction)
	Contributing factors (human) (Staffing/training; Cognitive load; Fail to do duty)

Table 2. Covered patient safety concepts for included classifications

Main concept	Definition	Medical device	HIT
Incident type	A term for classifying common events; for example, information input, incident types, information transfer problems.	2, (FDA-EPC, CTE), [3, 5]	3, (MI-ITC, CHIT-SP, TMPS-HIT), [2, 4, 15]
Contributing factors/ hazards	Conditions that play roles in developing incidents or increasing risk of incidents; for example, staffing or training.	2, (FDA-EPC, CAED), [3, 14]	4, (MI-ITC, CHIT-SP, TMPS-HIT), [2, 4, 7, 15]
Degree of harm	The severity and length of any harm, or any therapeutic implications; for example, mild, moderate, severe.	1, CAED, [14]	-
Processes (phase)	Specific phase of the medication process in which the medication incident had occurred; for example, prescribing, transcription and dispensing.	-	1, MI-ITC, [2]
IT systems	IT systems that were used in hospitals and community pharmacies; for example, automated dispensing cabinets, CPOE, website, EHR	-	1, MI-ITC, [2]

Table 3 describes other patient safety classifications that have HIT or medical device-related concepts. Concepts not addressed by included classifications may be included to these classifications in future versions using these classifications.

Table 3. HIT or medical device concepts according to various patient safety classifications

Classification name/ Reference	First level concepts	Second and third level concepts
ICPS/ [16]	Contributing factors /hazards (external factors)	Products, technology & infrastructure
Taxonomy for Radiation Treatment Errors (TRTE)/ [17]	Contributing factors /hazards	Technology factors (Poor design/incorrect operation; Malfunction*)
Taxonomy of Patient Safety in General Practice (TPSGP)/ [18]	Technical factors	Information salience and presentation Information availability/delays; Absence of retrieval cues/cues to action
Nursing Errors relating to Clinical Management taxonomy (NECM)/ [19]	Nursing care process	Technology applied/ required (Incorrect technique, Inappropriate equipment)
	Written communication	Incomplete chart; Omission in documentation
Diagnostic Error Evaluation and Research taxonomy (DEER)/ [20]	Performance	Technical errors*

* represents concepts that are covered in classifications such as CHIT-SP and TMPS-HIT

4. Discussion

We found six classifications in seven included articles mostly for adverse events and medication error subjects. The FDA-EPC, CAED, and CTE, respectively, were developed using the National Cancer Institute (NCI) Thesaurus, Clavien-Dindo, and FIN-TIERA tool [3, 5, 14]. The prior Magrabi's classification of Computer-related Patient Safety Incidents (CCPSI) [7] was utilized to construct the CHIT-SP [4], and the current CHIT-SP was used to develop the MI-ITC [2] and TMPS-HIT [15]. From the classifications that were used for developing the included classifications, Clavien-Dindo was used to determine the concepts of degree of harm [14], and the FIN-TIERA [5] was used to classify the incident types.

The included classifications cover different technologies. CTE covers EHR downtime and system-to-system interface or device failures [5]. TMPS-HIT includes event reporting system, help desk and EHRs [15] and MI-ITC includes information technology systems, automated dispensing cabinets, CPOE, order system, website, EHR, fax, infusion pump, laboratory diagnostic analyzer, medication administration registration, pharmacy bar code scanning system, pharmacy information system, prescription scanner and printers [2]. CHIT-SP includes Picture Archiving and Communication System (PACS), CPOE, Electronic Medical Record (EMR) and laboratory information systems [4]. EHR and CPOE are covered in at least two included classifications. The results show that the included classifications have good coverage on a variety of HIT systems.

HIT patient safety challenges are divided into design and development challenges, implementation and use challenges, monitoring, evaluation, and optimization challenges based on HIT life cycle [21]. HIT classifications such as MI-ITC, CHIT-SP and TMPS-HIT categorize HIT problems at different stages of the information cycle such as information input, information transfer, and information output problems [2, 4, 15]. Considering the classification of HIT-related patient safety problems, such as equipment failure and hazards, helps to classify HIT-related patient safety challenges.

Classifying patient safety concepts in the fields of HIT and medical devices allows physicians and researchers to identify the types of errors, adverse events, and contributing factors. Data about patients, incidents, contributory factors and root causes, devices/products that contribute to the incidents, discovery factors, mitigating factors, ameliorating factors, and actions taken/planned to reduce the risk of re-occurrence of similar incidents are considered important [8, 16]. These categories should all be utilized to collect various data on root causes, ameliorating factors, errors and events, mitigating considerations, and event outcomes. These concepts should be presented at reporting systems to improve preventive and recovery capacities, and eliminate the root causes of the events [8]. Most included classifications such as MI-ITC, FDA- EPC, CHIT-SP, CTE and TMPS-HIT cover the “incident type” [2-5, 15] and MI-ITC, FDA- EPC, CHIT-SP, CAED and TMPS-HIT cover “contributing factors/hazards” [2-4, 14, 15]. Then, the "degree of harm" is also used in only one classification (CAED) [14].

There are no classes for mitigating factors, actions taken to reduce risk, and ameliorating actions in these classifications. Considering these concepts by identifying new concepts and classes improves the reporting and analyzing patient safety events. Incident characteristics, organizational outcomes, detection, and patient characteristics were also not included in these classifications. If these concepts are considered, they will enrich these classifications.

For HIT, MI-ITC and TMPS-HIT are used for medications [2, 15], and TMPS-HIT is related to pediatrics [15]. For medical devices, CAED is for the DaVinci surgical system [14]. These findings highlight the limitations of application domain of these classifications and provide a direction for future research.

5. Conclusion

This study aimed to determine the existing patient safety classifications, patient safety subjects, and covered concepts in HIT and medical devices. The most commonly covered classes of concepts were contributing factors/hazards and incident type. By exploring additional potential concepts based on WHO patient safety classification, Clavien-Dindo, and CHIT-SP there would be a chance to construct richer and more fulfilling classifications in a wider range of medial domain subjects for HIT and medical devices. It is recommended to consider the concepts related to information technology that have been used in some levels of other medical domain classifications but are not included in HIT or medical device safety classifications. Incident type based on information input, transfer and output problems, and device operational issues, and contributing factors for human and machine are recommended mostly to be considered in HIT classification system because of their commonly utilization.

Acknowledgment

This study is a part of a Ph.D. dissertation supported by the Iran University of Medical Science (IUMS/SHMIS-98-1-37-14546).

This study received ethical approval from Research Ethics Committee of Iran University of Medical Science (IR.IUMS.REC.1398.274). The authors declare that there are no competing interests either financially or non-financially in this study.

References

[1] Donaldson MS, Corrigan JM, Kohn LT. To err is human: building a safer health system. 2000.
[2] Cheung K-C, van der Veen W, Bouvy ML, Wensing M, van den Bemt PM, de Smet PA. Classification of medication incidents associated with information technology. *Journal of the American Medical Informatics Association*. 2014;**21**(e1):e63-e70.
[3] Reed TL, Kaufman-Rivi D. FDA adverse event problem codes: Standardizing the classification of device and patient problems associated with medical device use. *Biomedical instrumentation & technology*. 2010;**44**(3):248-56.
[4] Magrabi F, Ong M-S, Runciman W, Coiera E. Using FDA reports to inform a classification for health information technology safety problems. *Journal of the American Medical Informatics Association*. 2012;**19**(1):45-53.
[5] Palojoki S, Saranto K, Lehtonen L. Reporting medical device safety incidents to regulatory authorities: an analysis and classification of technology-induced errors. *Health informatics journal*. 2019;**25**(3):731-40.
[6] Sadoughi F, Ahmadi M, Moghaddasi H, Sheikhtaheri A. Patient safety information system: purpose, structure and functions. *Journal of Mazandaran University of Medical Sciences*. 2011;**21**(85):174-88.
[7] Magrabi F, Ong MS, Runciman W, Coiera E. An analysis of computer-related patient safety incidents to inform the development of a classification. *Journal of the American Medical Informatics Association* : *JAMIA*. 2010;**17**(6):663-70.

[8] Sheikhtaheri A, Sadoughi F, Ahmadi M, Moghaddasi H. A framework of a patient safety information system for Iranian hospitals: lessons learned from Australia, England and the US. International journal of medical informatics. 2013;82(5):335-44.
[9] Bodenreider O. The unified medical language system (UMLS): integrating biomedical terminology. Nucleic acids research. 2004;32(suppl_1):D267-D70.
[10] Erickson SM, Wolcott J, Corrigan JM, Aspden P. Patient safety: achieving a new standard for care. 2003.
[11] Wang G, Hahn JF, Mangaser A, Roe DB, Steiner CP, Uecker DR. Method and apparatus for accessing medical data over a network. Google Patents; 2005.
[12] de Oliveira BGRB. Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist.
[13] Global atlas of medical devices 2017 [Available from: https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature.
[14] Gupta P, Schomburg J, Krishna S, Adejoro O, Wang Q, Marsh B, et al. Development of a Classification Scheme for Examining Adverse Events Associated with Medical Devices, Specifically the DaVinci Surgical System as Reported in the FDA MAUDE Database. Journal of Endourology. 2017;31(1):27-31.
[15] Wyatt KD, Benning TJ, Morgenthaler TI, Arteaga GM. Development of a Taxonomy for Medication-Related Patient Safety Events Related to Health Information Technology in Pediatrics. Applied clinical informatics. 2020;11(05):714-24.
[16] Conceptual framework for the international classification for patient safety version 1.1: final technical report January 2009. World Health Organization; 2010. Report No.: 606940937X.
[17] Lam C, Medlam G, Wighton A, Breen SL, Bissonnette JP, McGowan TS, et al. A Practice-based Taxonomy for Radiation Treatment Errors. Journal of medical imaging and radiation sciences. 2013;44(4):173-9.
[18] Kostopoulou O. From cognition to the system: developing a multilevel taxonomy of patient safety in general practice. Ergonomics. 2006;49(5-6):486-502.
[19] Tran DT, Johnson M. Classifying nursing errors in clinical management within an Australian hospital. International nursing review. 2010;57(4):454-62.
[20] Schiff GD, Kim S, Abrams R, Cosby K, Lambert B, Elstein AS, et al. Diagnosing diagnosis errors: lessons from a multi-institutional collaborative project. 2005.
[21] Sittig DF, Wright A, Coiera E, Magrabi F, Ratwani R, Bates DW, et al. Current challenges in health information technology–related patient safety. Health informatics journal. 2020;26(1):181-9.